510(k) SUMMARY

DEC 14 2012

CV-170 VIDEO SYSTEM CENTER

September 14, 2012

I. General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
  Establishment Registration No: 8010047

- Official Correspondent: Sheri L. Musgnung
  Associate Manager, Regulatory Affairs
  Olympus America Inc.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-3147
  FAX: 484-896-7128
  Email: sheri.musgnung@olympus.com

- Manufacturer: SHIRAKAWA OLYMPUS CO., LTD.
  3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
  Nishishirakawa-gun, Fukushima, Japan 961-8061
  Establishment Registration No: 3002808148

II. Device Identification

- Device Trade Name: CV-170 VIDEO SYSTEM CENTER
- Common Name: VIDEO SYSTEM CENTER
- Regulation Number: 876.1500
- Regulation Name: Endoscope and Accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: NTN (led light source)
  NWB (endoscope, accessories, narrow band spectrum)

III. Predicate Device Information

Model name	Applicant	510(k) No.
OLYMPUS CV-190 VIDEO SYSTEM CENTER	OLYMPUS MEDICAL SYSTEMS CORP.	K112680
OLYMPUS CLV-190 XENON LIGHT SOURCE	OLYMPUS MEDICAL SYSTEMS CORP.	K112680

IV. Device Description

The VIDEO SYSTEM CENTER OLYMPUS CV-170 is intended for endoscopic diagnosis, treatment and video observation.

The CV-170 is a device which integrates the video processor and the light source. Thus, the CV-170 itself could emit light, capture and process the endoscopic image, and transmit signal to display it on the monitor.

The main function of the CV-170 is NBI observation, LED lamp examination, Noise reduction function, Pre-freeze feature, and Color correction.

V. Indications for Use

This video system center is intended to be used with OLYMPUS video converter, camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.

VI. Comparison of Technological Characteristics

The main difference of the subject device compared to the predicate devices is the examination lamp type. Unlike the predicate device, CLV-190 XENON LIGHT SOURCE, the subject device utilize LED as the examination lamp.

VII. Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for

Software Contained in Medical Devices." The device software is considered a MODERATE Level of Concern.

The following standards have been applied to the CV-170:

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-2-18
- IEC 60601-1-2
- ISO 14971

VIII. Conclusion

When compared to the predicate device, the CV-170 VIDEO SYSTEM CENTER does not incorporate any significant changes in intended use, method of operation, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 14, 2012

OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Sheri L. Musgnung
Associate Manager, Regulatory Affairs
Olympus America, Inc.
3500 Corporate Parkway, P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K122831
Trade/Device Name: CV-170 VIDEO SYSTEM CENTER
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NTN, NWB, FET
Dated: September 14, 2012
Received: September 17, 2012

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122831

Device Name: CV-170 VIDEO SYSTEM CENTER

Indications For Use:

This video system center is intended to be used with OLYMPUS video converter, camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122831